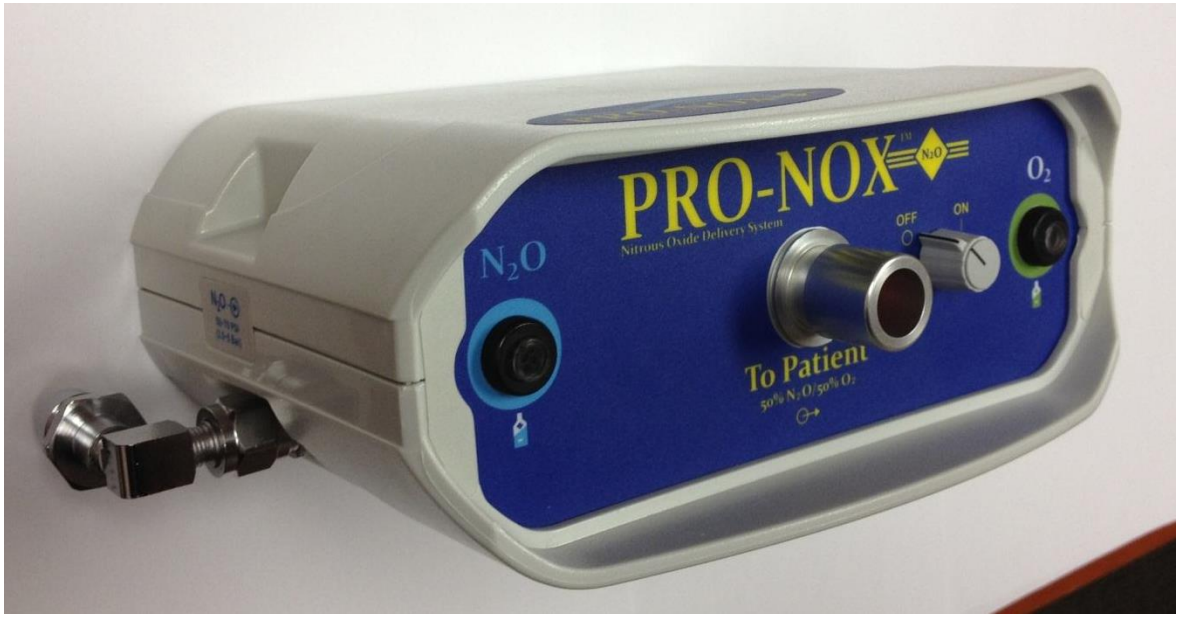
PRO-NOX™

Nitrous Oxide Delivery System

CMI-0100-PNX



Made for

Carestream Medical International Ltd.

USER MANUAL

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1. WELCOME TO THE PRO-NOX™ NITROUS OXIDE DELIVERY SYSTEM

1.1 INTRODUCTION

The PRO-NOX Nitrous Oxide Delivery System is a pneumatically driven gas mixer designed to deliver a 50% Oxygen and 50% Nitrous Oxide gas mixture to adult and pediatric patients for the relief of pain in a medical setting.

The demand valve integrated into the main device housing minimizes risk of patient-to-patient cross-contamination.

Minimal user controls and enhanced safety features make this the safest nitrous oxide mixer available.

1.2 UNPACKING AND INSPECTION

Inspect packaging for damage – document any damage seen

Remove all contents from the PRO-NOX packaging, and ensure all of the following are included

PRO-NOX Nitrous Oxide Delivery Device
6-foot nitrous oxide high-pressure hose
6-foot oxygen high-pressure hose
Single-use patient circuit including mouthpiece and nose clip
Product registration card
This User Manual

NOTE: If any components are missing from the shipping carton, immediately call the supplier with the packing slip number, your original purchase order number and the description of the item which is missing.

1.3 ABREVIATIONS AND SYMBOLS USED IN THIS MANUAL

N_2O	Nitrous Oxide
O_2	Oxygen
DISS	Diameter Index Safety System
PSI	Pounds per Square Inch pressure - equivalent to PSIG (gas) for the purposes of this manual
LPM	Litres per minute flow
cmH2O	Centimetres of water pressure
$^{\circ}C$	Degrees Celsius
$^{\circ}F$	Degrees Fahrenheit
mm	Millimeter
mL	Millilitre
lb	Pound
kg	Kilogram

⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury
⚠ CAUTION	Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury or damage to equipment.

1.4 READ ALL INSTRUCTIONS PRIOR TO USE

⚠ CAUTION	Federal (USA) Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) who has appropriate training and experience.

1.5 WARNINGS AND CAUTIONS

⚠WARNING

- This device is restricted to sale by or on the order of a licenced healthcare practitioner
- Only trained, qualified medical personnel should operate this device
- Use this device only for its intended purpose as indicated in this manual
- Ensure absence of contra-indications before administering nitrous oxide
- Monitor patient closely while delivering nitrous oxide and afterward until effects are cleared
- DO NOT obstruct patient ambient-air inlet on back of machine
- If audible alarm sounds continuously, DISCONTINUE USE AND SHUT OFF SOURCE GAS
- DO NOT use this device or handle compressed gas near any open flame
- ALWAYS follow ANSI and CGA standards when handling compressed medical gases
- Servicing of this device should only be done by a qualified and authorized service technician. ANY UNAUTHORIZED DISASSEMBLY WILL INVALIDATE THE WARRANTY
- The nitrous oxide cylinder should be operated in an upright position. If it is in a valve-down position while the cylinder valve is open, liquid may be expelled through the vent passages. This liquid nitrous oxide can cause burns by freezing exposed skin
- Never allow oil or grease to come into contact with any part of the cylinders, regulators or PRO-NOX™ device
- Where scavenging is being used, ensure the patient is maintaining a seal with the mouthpiece or mask during exhalation
- *** NEVER HOLD THE MOUTHPIECE OR MASK IN PLACE FOR THE PATIENT. THE PATIENT MUST DO THIS ON THEIR OWN. IF THE PATIENT CANNOT, CONSIDER ALTERNATIVE FORMS OF ANALGESIA

⚠CAUTION
• Turn off compressed gas source prior to storage of PRO-NOX™ device • Store PRO-NOX™ in a clean, dry area when not in use • NOT MRI COMPATIBLE • Ensure all gas fittings are tight and leak free • Adding components (filters, circuit extensions) to circuit may increase inspiratory resistance If patient complains of difficulty in breathing through device, remove additional components • Instruct patient to breathe out into mask or mouthpiece, and to maintain seal throughout respiratory cycle • Always open cylinder valves slowly and completely • After use, always ensure that all components are cleaned or replaced in accordance with the instructions provided in this manual • Use this device in areas with appropriate ventilation to minimize atmospheric exposure to inhaled analgesic

1.6 INDICATIONS FOR USE

The PRO-NOX™ Nitrous Oxide Delivery System is intended to provide a mixture of 50% nitrous oxide and 50% oxygen, on demand, to a conscious, spontaneously breathing patient for the relief of pain due to trauma or other conditions where inhalation analgesia is clinically indicated.

The device is suitable for:

- Pre-hospital use (ambulance), and
- In-hospital use (ER, Labour and Delivery etc.)
- Physician's offices
- Birthing centers
- Clinics
- Esthetics centers

1.7 CONTRAINDICATIONS

- Hypersensitivity to nitrous oxide mixtures
- Head injuries with impaired consciousness
- Maxillofacial injuries
- Artificial, traumatic or spontaneous pneumothorax
- Air embolism
- Middle ear occlusion, ear infection
- Decompression sickness
- Severe abdominal distension secondary to intra-abdominal air / intestinal obstruction
- Inability of patient to follow directions
- Inability of patient to hold own delivery device (mouthpiece or mask)

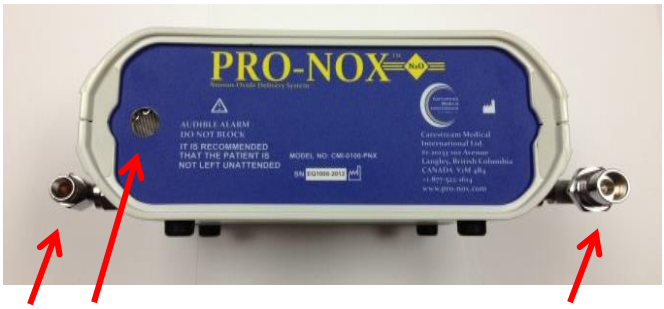
⚠ WARNING

Nitrous Oxide/Oxygen (N_2O / O_2) mixtures must never be used in any condition where air is trapped in the body and expansion (up to 3x original size) would be dangerous. For example, it will exacerbate pneumothorax and increase pressure from any intracranial air. Air in any other cavities such as the sinuses, middle ear and gut may also expand.

1.8 PRODUCT DESCRIPTION

The PRO-NOX™ System is designed to operate on medical nitrous oxide and medical oxygen from cylinders and/or medical gas piping systems. Supply gas shall be 50-70 PSI and able to supply 100 LPM flow at these pressures.

(2) (4) (1) (3)



(6) (7) (5)

(1) ON/OFF switch. With switch turned to ON and source gases connected, the demand valve will activate with -2.5 cmH2O inspiratory pressure. With switch in OFF position, the demand valve is inactive, and patient will breathe ambient air via opening at rear of device (7)

(2) Nitrous oxide and (3) Oxygen supply pressure indicators. 'Light up' green when pressurized with the indicated gas. These also serve as visual "flashing" indicators if low source gas pressure alarm is activated.

NOTE: the visual indicator will remain 'lit' with tank turned off if internals remain pressurized.

(4) Outlet of mixed PRO-NOX 50/50 gas to patient. 22mm OD connection for attachment of patient circuit

(5) DISS gas inlet connection for nitrous oxide source gas

(6) DISS gas inlet connection for oxygen source gas

The delivered gas mixture is pre-set at 50% nitrous oxide / 50% oxygen. Neither the patient nor medical personnel are able to adjust this ratio, eliminating the risk of delivering a hypoxic mixture.

The gas-specific built-in alarm systems will generate both visual and audible alarms should either the nitrous oxide or oxygen source pressure fall below 40 PSI, and the demand valve will no longer activate should either the nitrous oxide or oxygen source pressure fall below 35 PSI.

The device is also equipped with a secondary “fail safe” circuit that will activate a continuous audible alarm and disable the demand valve should internal malfunction occur in the mixer or any internal hoses rupture or kink.

⚠ WARNING

THE PRO-NOX™ NITROUS OXIDE DELIVERY SYSTEM IS CONSIDERED A CRITICAL DEVICE, AND ITS COMPONENTS CONSIDERED CRITICAL COMPONENTS. ONLY THOSE MEDICAL PERSONNEL TRAINED IN THE OPERATION OF NITROUS OXIDE/OXYGEN ANALGESIC GAS DELIVERY SYSTEMS SHOULD USE THIS EQUIPMENT. THOROUGHLY REVIEW THE INSTRUCTION MANUAL BEFORE USE.

1.9 PERFORMANCE SPECIFICATIONS

(Minimum) Peak Flow rate	120 LPM
Inhalation Resistance	0 to -6 cmH_2O @ 60 LPM
Exhalation Resistance	0 to 6 cmH_2O @ 60 LPM
Input Pressure	50 – 70 PSI (3.5-4.8 Bar)
Oxygen Concentration	42.5 to 57.5%
Initiation Pressure	-2.5 cmH_2O
Operating Temperature	41°F to 104°F (5°C to 40°C)
Storage Temp	-40°F to 140°F (-40°C to 60°C)
Nitrous Oxide Input Connection	CGA1040 DISS
Oxygen Input Connection	CGA1240 DISS
Patient Connector	15/22 mm
Patient Circuit	Single Use Patient Circuit c/w Scavenging port and filter
Patient Valve Dead Space	8 ml
Weight	53 oz. (1.5 Kg)
Dimensions W x D x H :	8.9 x 6.6 x 3.9 (inches) 226 x 168 x 99 (mm)

2. PREPARATION FOR USE

2.1 PRE-USE ASSEMBLY

If the PRO-NOX™ is being mounted on a wall arm or rolling stand, attach mounting plate to the PRO-NOX™ unit as described in the instructions that come with the mount.

Attach high-pressure hoses to the appropriate inlet DISS connections on the PRO-NOX™.
*** HAND-TIGHT ONLY ***

⚠ WARNING — Using a wrench or excessive force in tightening the supply hose may damage the seal or the thread of the connection.

Connect hoses to gas source (wall outlets or cylinder regulators).

Attach patient circuit to the patient outlet on the front of the PRO-NOX™.

If scavenging exhaled gases, attach scavenging tubing to exhalation port of patient valve and connect distal end of tubing to anesthetic gas scavenging system or (optional) PRO-NOX™ active scavenging system.

2.2 PRE-USE FUNCTIONAL TESTS

Perform these tests before putting PRO-NOX™ unit into service, and then every 6 months after.

Where you are directed to simulate inspiration, you can use a large syringe (ex. 500 cc calibration syringe) or a vacuum source set to approx. 30 Lpm connected to patient valve.

[1] Turn PRO-NOX™ ON/OFF control to OFF

[2] If using cylinder(s), open cylinder yoke fully.

NOTE: a whistling may be heard when the source gas is first turned on. This is an internal oxygen bleed that will last less than 15 seconds, until internal components are properly pressurized.

[3] Note that visual indicators ‘light up’.

[4] Attach machine end of patient circuit to ‘TO PATIENT’ port.

⚠ CAUTION Adding components (filters, circuit extensions) to circuit may increase inspiratory resistance. If patient complains of difficulty in breathing through device, remove additional components.

⚠ CAUTION Ensure all fittings are secure and that any scavenging attachments are in place and functioning

Demand Valve Function

[5] Simulate pt. inspiration with ON/OFF control in the OFF position. Demand valve should not activate. You will be able to draw ambient air via rear port on PRO-NOX™.

[6] Turn PRO-NOX™ ON/OFF control to ON

[7] Simulate inspiration (draw approx. 30 Lpm for minimum 1 second). You should hear gas flow as the demand valve is activated. The demand valve should close when inspiration is stopped.

Low Source Pressure Alarms and Safety Shut-offs

[8] Disconnect O_2 from gas supply - turn tank off at yoke, or disconnect high-pressure supply hose at wall outlet.

NOTE: Audible and visual alarms are activated as pressure within the PRO-NOX™ unit falls below 40 PSI. **O_2 visual indicator and alarm cycle at 180 beats/min**.

Demand valve ceases to function as O_2 supply pressure drop below 35 PSI.

** You may need to simulate several patient inspirations to get drop in gas pressure and alarm activation.

NOTE: Audible alarm will cease once O_2 pressure within the PRO-NOX™ unit drops below a threshold level. Visual indicator will cease to flash and will remain in the 'unlit' state.

[9] Reconnect oxygen supply gas to unit.

[10] Repeat steps 8 through 10 with the N_2O supply.

NOTE: **N_2O audible alarm and visual indicator will cycle at 48 beats/min**. They will continue to cycle until the N_2O pressure is restored or the Oxygen supply is turned off or depleted. Turning off the PRO-NOX will not silence the alarm.

*** To assess the specific PSI at which the low supply pressure alarms and shut-offs are activated, you need adjustable supply pressure regulators. Slowly decrease supply pressure until the feature is activated. You may need to activate the demand valve to depressurize the PRO-NOX internals as you decrease the supply pressure setting.

If using a rolling stand, ensure both gas supplies are connected and functioning, tanks are turned off at the yoke, and a new patient circuit is connected. Store in a clean, dry environment until next patient use.

If PRO-NOX™ is wall-mounted, ensure both gas supply hoses are connected and functioning, and a new patient circuit is connected.

3. OPERATING INSTRUCTIONS

3.1 ON/OFF SELECTOR

In the ON position, a patient inspiratory effort will activate the demand valve and deliver the Nitrous Oxide/Oxygen gas mixture. In the OFF position, patient efforts will draw ambient air via the port on the back of the machine.

3.2 DEMAND VALVE

The device is equipped with a demand system providing a 50% nitrous oxide / 50% oxygen mixture to spontaneously breathing patients via the patient mouthpiece or mask.

An inspiratory effort by the patient will open the demand valve and the gas mixture will flow to the patient matching the patient's inspiratory flow demands up to 120 Lpm.

3.3 GAS SUPPLY VISUAL INDICATORS

Located on the front panel, the O_2 visual indicator shows green when oxygen is supplied to the unit at a sufficient pressure, and the N_2O visual indicator shows green when nitrous oxide is supplied to the unit at a sufficient pressure. Used in conjunction with the low supply pressure alarms, these indicators provide additional reference for the operator as to the gas supply status.

ON OFF

3.4 LOW SUPPLY PRESSURE ALARMS

The alarm system will generate a 48 beat-per-minute visual (the N2O indicator will flash green) and audible alarm should nitrous oxide supply pressure fall below 40 PSI, and generate a 180 beat-per-minute visual (the O2 indicator will flash green) and audible alarm should oxygen supply pressure fall below 40 PSI.

Deep, fast inspiration may cause the low-pressure alarm to 'chirp' as the internal pressures drop due to high patient flow demand. This will cease as inspiratory flow demand slows. The patient should be encouraged to take slow deep breaths to maximize analgesic effect while minimizing hyperventilation.

3.5 LOW SUPPLY PRESSURE SHUT-OFF

The demand valve will no longer activate if either nitrous oxide or oxygen source pressure falls below 35-37 PSI. This indicates that the source gas is exhausted to the point where the device will no longer function as indicated.

As the oxygen source pressure drops below 35-37 PSI, the demand valve shuts down and the O_2 supply indicator will go from flashing to 'off'. The audible alarm ceases. The N_2O supply indicator will remain 'on'.

As the nitrous oxide source pressure drops below 35-37 psi, the demand valve shuts down and the N_2O pressure indicator and audible alarm continue to cycle at 48 bpm. The O_2 supply indicator will remain 'on'. The low N_2O alarm will continue until the O_2 supply is depleted or disconnected.

⚠ CAUTION

It is recommended that the patient remove the mouthpiece or mask if the demand valve is shut off. If they do not, the patient will still be able to draw ambient air via the rear port of the device.

4. MAINTENANCE

4.1 ROUTINE CHECKS

Inspection of the PRO-NOX™ Nitrous Oxide Delivery System and checking of the device to ensure functioning Low Supply Pressure Alarms and Shut-offs should be performed on a regular basis, minimally every 6 months (see Section 2.2 PRE-USE FUNCTIONAL CHECKS), and it is recommended that a record of these checks be maintained for each unit. A sample PRO-NOX™ checkout sheet is included at the end of this manual. Beyond this, analysis of the patient gas mixture should be done once/year to ensure delivered gases are within specified range.

*** More in-depth testing of the alarm and shut-off thresholds should be performed with the use of adjustable pressure regulators whenever proper function of the safety mechanisms is questioned. Slowly decrease the source pressure while activating the demand valve until each safety feature is activated.

⚠ WARNING

Units with test pressures or gas delivery outside of the ranges listed in the product specifications should not be used.

This PRO-NOX™ device is not designed for field service beyond that indicated in this manual. Any attempt to modify or repair this unit will make void the product warranty. If you have a unit that requires servicing, contact your local distributor prior to returning the unit.

4.2 CLEANING PROCEDURES

Routine cleaning of the device shall be undertaken to maintain the device in a useable and sanitary condition.

Patient circuit is intended for single use and shall be discarded after each patient use in accordance with local protocols and replaced with a new circuit. The patient interface (mouthpiece or mask) shall be disposed of or cleaned between patients as indicated. Mouthpieces provided with the patient circuits are to be disposed of between patients.

All other components should be wiped clean with a mild soap solution or hard surface disinfectant suitable for polycarbonates. Under no circumstances should the complete unit be allowed to be soaked or immersed in cleaning solutions.

Detailed cleaning procedures are as follows:

1. Ensure that the device is disconnected from the gas supply source.
2. Remove the single patient use circuit from the device and dispose of safely in accordance with local protocols.
3. Remove N_2O and O_2 input hoses and wipe clean with a mild soap or hard surface disinfectant. Ensure no cleaning solution enters the hoses.
4. The PRO-NOX enclosure can be wiped over with a soft cloth and mild soap solution or hard surface disinfectant.
5. If there is ingrained contamination a soft bristled brush may be used.
6. Dry all components thoroughly.
7. Surface disinfection may be performed using disinfectant wipes compatible with polycarbonate materials. Ex. CaviWipes™ or Accel™ products with 0.5% accelerated hydrogen peroxide. Disinfect as per disinfection product instructions.
8. Attach a new patient circuit and connect the unit to the gas supply. Check function prior to packaging for emergency use.

⚠ WARNING

Do not attempt to clean or sterilize any components that are designated as disposable or single-patient-use as immersion of these items into a sterilizing solution can cause degeneration of the materials.

5. ACCESSORIES & CONSUMABLES

PRO-NOX™ Nitrous Oxide Delivery System Unit

CMI-0100-PNX-US PRO-NOX™ unit with 6-ft high pressure hoses, one single-patient-use circuit, manual. 2-year warranty.

Circuit Components

WES9303 Disposable 6-ft (1.8 m) Patient Circuit c/w filter, mouthpiece and nose clips - Case of 20

CMI-0160-PNX Scavenging tubing – 100 ft roll, magenta, 19mm cuffs every 12 inches

PRO-NOX™ Mounting Solutions

CMI-0110A-PNX Rolling stand – includes
- 1 rolling stand with handle, basket, and cylinder holder to mount one oxygen and one nitrous oxide e-cylinder to rolling stand
- 1 stainless steel mounting plate to secure PRO-NOX™ unit onto rolling stand (c/w circuit holder)

CMI-0120A-PNX Wall-mount – includes
- 1 aluminum wall-mounted 8-inch swing arm
- 1 stainless steel mounting plate to attach PRO-NOX™ unit to wall-mount

Nitrous Oxide Delivery System

For Mounting PRO-NOX™ with Pre-existing 5/8" Post Mounts

Mounting solutions when replacing older-generation mixers

CMI-0122-PNX	Stainless steel mounting plate to mount PRO-NOX™ unit on Matrx Nitronox® wall mount – with 2.5 inch x 5/8 inch post
CMI-0113-PNX	Stainless steel mounting plate to mount PRO-NOX™ unit on Matrx Nitronox rolling stand – with 15 inch x 5/8 inch post (requires Nitronox post-collar)

Active Scavenger

GD-1925	Active Scavenger with 19mm exhaled-gas inlet, 3/8" barb for suction hose attachment, flow control knob and pressure relief ports. Basket mount.

6.0 MANUFACTURER:

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7.0 WARRANTY

WARRANTY

Carestream Medical International Ltd (CMI) warrants to the original purchaser of this PRO-NOX™ Nitrous Oxide Delivery System that it is free from defects in material and workmanship for a period of two years from the date of purchase. This warranty is extended only to the original purchaser of this product from CMI or an authorized PRO-NOX™ distributor.

In the event of a defect, malfunction, or failure of this PRO-NOX™ unit within the two-year period, and upon notification of the defect in writing by the purchaser, CMI will repair or replace the product (at the sole discretion of CMI) at no cost to the purchaser. All shipping costs shall be borne by the purchaser.

This warranty shall be void if the equipment is damaged as a result of abuse, neglect, accident, or failure to follow operating or maintenance instructions.

This warranty shall become void if any repairs or alterations to the warranted product beyond that described in the user manual are undertaken without the prior authorization of CMI.

Under no circumstances will CMI be liable for consequential damage, loss, or expense arising directly or indirectly from the use of this device.

This warranty is given in lieu of all other warranties expressed or implied, and Carestream Medical International Ltd. neither assumes, nor authorizes any person to assume on CMI's behalf, any liability beyond that stated herein.. This warranty gives no specific legal rights. You may also have other rights which may vary according to local regulations.

Nitrous Oxide Delivery System

Appendix A – Sample PRO-NOX Checkout Procedure

PRO-NOX #_____

	Attach PRO-NOX to source gas cylinders	Both inlet pressure indicators should be 'on'	Connect scavenging circuit. Turn PRO-NOX on. Attach syringe (min 500 ml) and slowly pull back	Demand valve activates easily	Pull back syringe, approximating 30 lpm demand flow	Demand valve meets 30 lpm flow demand and closes when 'insp' ends	Slowly decrease source pressure while activating demand valve - Audible and visual indicators noted when inlet pressure drops below 40 PSI	O2 side 180 bpm	N2O side 48 bpm	Continue to decrease source pressure. Demand valve shuts off when inlet pressure drops below 35-37 PSI	O2 side	N2O side	Device is clean. New pt. circuit attached, and PRO-NOX attached to full cylinders or wall source	Initials
Date														